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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,210	02/09/2001	Monica M. Jablonski	6704-11	6997

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EXAMINER
FAY, ZOHREH A

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/780,210	Jablonski et al.
Examiner	**Art Unit**
Zohreh Fay	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-24 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Claims 1-24 are presented for examination.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 5 and 18 are rejected under 35 U.S.C. 102 (b) as being anticipated by Wheeler et al.. Wheeler et al. Teach the use brimonidine in a pharmaceutical formulation for the prevention of damage to the retinal. The above reference makes clear that the claimed composition and the use thereof is old and well known. Such composition is inherently kept in a pharmaceutically acceptable kit. The kit of the claimed invention in the absence of any unusual feature reads on the kit taught by the prior art. The use of a label or instruction on a kit does not create a patentably distinct kit.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-4, 6-17 and 19-24 are rejected under 35 U.S.C. 103 as being unpatentable over Wheeler et al. , Sallman et al. (U.S. Patent 5, 891,913) and Wen et al. (U.S. Patent 6, 066,675).

Wheeler et al. Teach the protective effect of brominidine on retinal photoreceptor cells. See the entire abstract. Sallman et al. Teach the use of the secondary active ingredients such as

diclofenac in an ophthalmic formulation for the treatment of inflammatory conditions of the eye for any reasons. See page 4, line 36-44. The use of the wetting agents and ophthalmic carriers is also taught by the above reference. See page 5, lines 28-50. Wen et al. Teach the use of growth factor for the treatment of retinal degeneration. See page 4, lines18-24. The primary reference differs from the claimed invention in the presence of the secondary ingredients and ophthalmic carriers. It would have been obvious for a person skilled in the art to incorporate such teaching into the primary reference, considering that Sallmon et al. Teach the use of the claimed antiinflammatory agents for the treatment of ophthalmic inflammation due to any cause. Such reference also teach the claimed ophthalmic wetting agents and carriers. Steinberg et al. Teaches the growth factor of claim 19 as an agent used for the treatment of retinal degeneration.

One skilled in the art would have been motivated to combine the teachings of the above references, they in combination relate to the use the claimed compound brimonidine as an agent used for the treatment of retinal degeneration and also the use of the secondary agents in the ophthalmic filed for the prevention of inflammation and retinal degeneration as old and well known. The detrmination of optimum proportions or amounts and the use of brominidine derivatives is considered to be within the skill if the artisan. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-17 and 19-24 are properly rejected under 35 U.S.C. 103.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Fay whose telephone number is (703) 308-4604.

JOHN FAY
PRIMARY EXAMINER
GROUP 1200

John Fay